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Promoting Heart Health in Canada:

A Focus on Cholesterol

REPORT OF THE WORKING GROUP ON THE PREVENTION AND CONTROL OF CARDIOVASCULAR DISEASE

Ottawa, November 1991

Canada

PROMOTING HEART HEALTH IN CANADA: A FOCUS ON CHOLESTEROL

Report of the Working Group on the Prevention and Control of Cardiovascular Disease

submitted to

The Federal-Provincial Advisory Committee on Community Health

Ottawa, November, 1992

PROMOTING HEART HEALTH IN CANADA:
A FOCUS ON CHOLESTEROL

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FOREWORD

The "A Focus on Cholesterol" report of the Federal Provincial Working Group on the Prevention and Control of Cardiovascular Disease examines the cholesterol issue from a public health perspective within the context of a multifactorial approach to cardiovascular disease prevention. The controversy that surrounds the topic is, in part, due to the lack of a long-term policy that reflects a consensus among the numerous stakeholders in the public, private and voluntary sectors and in the health professions.

Defining issues and sketching strategic options are a place to start to develop a policy. I trust that the Advisory Committee on Community Health and the provincial jurisdictions to which this report is primarily addressed, will consider it as a working document that will need further elaboration. Ideally it should help define an agreement on some common goals and approaches to be pursued at the national level and also assist the provinces in defining their own strategies.

Without exception, the Working Group has encountered excellent cooperation and collaboration from public and private agencies. I would like to thank the numerous individuals and organizations that have given advice to the Working Group.

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of Cardiovascular Disease
Ottawa, November, 1991

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1. EXECUTIVE SUMMARY

1.1 The report of the Working Group on the Prevention and Control of Cardiovascular Disease, *Promoting Heart Health in Canada: A Focus on Cholesterol* provides a policy framework for federal, provincial and territorial jurisdictions to address the cholesterol issue in the broader context of cardiovascular disease prevention.

1.2 The Working Group was charged by the Federal Provincial Advisory Committee on Community Health to develop a public health strategy to deal with the major issues of blood cholesterol as it pertains to cardiovascular disease risk. The Working Group was asked to assess the implications of the recommendations from the Canadian Consensus Conference on Cholesterol (1988), which proposed a two-pronged approach to dealing with the high prevalence of elevated blood cholesterol in the Canadian population. The Consensus Conference provided the beginnings of a policy framework and heightened public and professional awareness of the cholesterol issue in Canada. The Working Group engaged in a Canada-wide consultation to establish the views of provincial and territorial jurisdictions, voluntary agencies, professional associations, the private sector and individual experts.

1.3 The Working Group found that many provincial jurisdictions have evaluation and treatment guidelines for hypercholesterolemia. Some of these guidelines have been recognized as provincial policy; others have been issued by voluntary agencies and/or professional associations. While there is some commonality among guidelines, they differ enough to cause confusion in the professional community. Conflicting accounts in the popular media have confused the public on the meaning and importance of cholesterol as a risk factor, particularly as it pertains to the relationship of diet, cholesterol and heart disease. Increased awareness among physicians and the public of cholesterol as a risk factor is creating increasing demand for evaluation and treatment health care resources.

1.4 It is estimated that more than eight million Canadians are at increased risk of ischemic heart disease due to elevated levels of blood cholesterol. Among these, three million are at high risk. This presents a significant opportunity for prevention because a main cause of this high prevalence is a diet high in

total fat and in saturated fat. A comprehensive strategy that combines a dietary and public education approach with the identification and management of individuals at high risk would significantly reduce premature ischemic heart disease, sickness and disability and would enhance the quality of life of many Canadians.

1.5 The cholesterol issue can and should be managed, but leadership on the part of federal, provincial and territorial jurisdictions is required to support and coordinate activities of numerous stakeholders: government departments, voluntary health agencies, professional organizations and the private sector. Implementing the policy described in this report will require a five to ten year phase-in period to allow the different stakeholders time to develop the necessary components of the policy: public and professional education, evaluation and treatment guidelines, standardization of laboratory analysis of blood lipids, and an intersectoral approach to the promotion of an environment that is supportive of dietary change. The Working Group recommends that provincial and territorial health departments assume responsibility for coordination of policy and program development in the context of heart health programs.

1.6 Public education programs on cholesterol and nutrition should provide clear and consistent messages to the public, including specific information on blood cholesterol as a risk factor and advice on how to comply with the new Nutrition Recommendations recently released by the Department of National Health and Welfare.

1.7 National guidelines for evaluation and treatment of individuals at risk are needed to clarify the confusion which now exists among health professionals. This is an urgent requirement and development of these guidelines by relevant professional associations should be expedited. Implementation of the guidelines requires enhancement of knowledge and skills of health professionals. There appears to be a lack of trained dietitians to respond to the projected demand for nutritional counselling.

1.8 There is a need to improve the accuracy and precision of blood lipid analysis through a coordinated program of standardization and of internal and external quality control. This will result in increased effectiveness in the identification, evaluation and treatment of Canadians at risk. In reporting an

individual's results to a physician, Canadian laboratories should adopt the cut-off points for risk proposed by the Canadian Consensus Conference on Cholesterol.

2. MANDATE AND PROCESS

2.1 The Working Group's task was to identify issues and necessary approaches for a public health approach to the control of elevated blood cholesterol and other lipids in the context of a comprehensive approach to cardiovascular disease prevention.

2.2 In discharging its task, the Working Group has held consultations with representatives of provincial governments, health professional associations, voluntary health organizations, the private sector and with other federal departments. The consultations were informal, but formal briefings were often prepared by those consulted.

2.3 The Working Group has also held consultations with national and international experts and has held technical consultations with lipidologists, clinical chemists and other health professionals.

3. CHOLESTEROL AS A HEALTH POLICY ISSUE

A controversial issue...

3.1 Few disease prevention issues have aroused as much controversy in recent years as the assessment of risk due to elevated blood cholesterol and the approaches to prevention and control both in individuals and in populations. This controversy arises from the complexity of addressing the issue in a comprehensive manner, concerns about health costs and differences of opinion on the scientific basis for prevention and control.

High rates of CVD...

3.2 Canadian men and women experience ischemic heart disease at much higher rates than other industrialized countries such as France and Japan. In Canada, the rates of cardiovascular disease and its major component, ischemic heart disease, are higher in the eastern than in the western provinces and also higher in the lower socio-economic groups (Nicholls, 1986, 1988; Wigle and Mao, 1980). Although we are currently witnessing a yearly decline of 3% ischemic heart disease and stroke rates, these diseases remain the main cause of premature death and one of the major causes of disability prior to age 65 in both men and women. After the age of 65, ischemic heart disease is the major cause of death (Federal Provincial Working Group on The Prevention and Control of Cardiovascular Disease, 1987). Scientific knowledge gained in the last 30 years shows that the major risk factors for ischemic heart disease (smoking, high blood pressure and elevated blood cholesterol) are preventable or can be controlled (Kaplan and Stamler, 1983). Because of the high prevalence of these risk factors in the Canadian population, an integrated public health approach to prevention should result in major health gains (Federal Provincial Working Group on the Prevention and Control of Cardiovascular Disease, 1987).

Opportunity for prevention...

3.3 The potential for prevention is indeed significant. Analyses of the results of ischemic heart disease primary prevention trials and observational studies, involving many thousands of subjects, followed over a number of years, provide consistent evidence that significant reductions (10% to 30%) of ischemic heart disease events would be obtainable in Canada in the next decade with relatively modest reduction of the blood cholesterol of most adult Canadians (MacMahon and Peto, 1988; Tyroler, 1985, 1987). These estimates of the potential for ischemic heart disease reduction are above and beyond the

current rates of decline. With further reductions in smoking, high blood pressure, obesity and sedentary lifestyle, the benefits should be much greater (Little and Horlick, 1989; Kottke et al., 1985).

Canadian Consensus Conference on Cholesterol...

3.4 The Canadian Consensus Conference on Cholesterol (1988) provided a comprehensive, authoritative scientific review of the many facets of the cholesterol issue. Whether the level of blood cholesterol is a risk factor for ischemic heart disease is no longer an issue. There is firm evidence linking reduction of blood cholesterol levels with reduced rates of illness and death from ischemic heart disease. The Conference proposed interventions which require a public health approach involving many sectors of society, including different levels of government and the private sector, as well as health professionals and voluntary organizations. There is considerable knowledge and experience on how to intervene, but there is still much to learn. The potential impact on health care costs of interventional approaches involving large segments of the Canadian population is considerable.

Mass hypercholesterolemia and mass atherosclerosis...

3.5 There is general agreement on the desirability of reducing blood cholesterol levels and the potential benefits. Atherosclerotic ischemic heart disease is a public health phenomenon of affluent cultures. Epidemiological comparisons suggest that mass hypercholesterolemia is a prime requisite for mass atherosclerosis. Diets high in total fat and in saturated fat, appear to be the main factor leading to mass hyperlipidemia (Blackburn, 1979). Accordingly, the primary approach to the prevention of hypercholesterolemia should be a population/health promotion strategy directed towards reduction of dietary fat intake (Horlick, 1989; Toronto Working Group on Cholesterol Policy, 1989; Department of National Health and Welfare, 1990a). Implementation of an effective dietary strategy that facilitates healthy choices by consumers presents a policy challenge. The policy should be intersectoral and involve different levels of government, the private sector, voluntary health agencies and professional associations.

Population approaches... gaining experience...

3.6 The value of the population approach for prevention of ischemic heart disease is well recognized. Health promotion approaches to smoking cessation and better nutrition, coupled with improvements in the management of high blood pressure, are considered to be the main factors in the reduction of ischemic heart disease mortality in North America (Stern, 1979; Goldman and Cook, 1984). There is experience in the develop-

ment and in the evaluation of the impact of comprehensive multifactorial interventions on ischemic heart disease prevention at the community level (Puska et al., 1983; Farqhuar, 1977). In Canada, the Federal Provincial Heart Health Initiative is promoting the development and evaluation of model community interventions through provincial departments of health and helping them the share program experience. The latter is being accomplished at the national level through the Canadian Heart Health Network (Lauzon, 1990) and at the international level through participation in the W.H.O. Countrywide Integrated Noncommunicable Disease Intervention (CINDI) program (Stachenko, 1990).

3.7 While it is well accepted that most cases of heart disease originate among those with moderate to high risk with respect to cholesterol level (Rose, 1981), the feasibility of intervening cost-effectively with dietary approaches on individuals in this range (5.2-6.2 mmol/L) is not fully known. Differences of opinion exist on the benefits of intervention in this risk range relative to the costs, and to the potential for undue medicalization and "labelling" of individuals at risk (Toronto Working Group on Cholesterol Policy, 1989; Logan, 1990; Little, Horlick, 1989).

Priorities for identification...

3.8 There is consensus that middle-aged men and persons with other risk factors (smoking, high blood pressure, obesity, diabetes, familial history of hypercholesterolemia or of premature heart disease) constitute a priority for identification. There is tangible scientific proof of the value of intervention in men and that the increase in risk from hypercholesterolemia is greater in the presence of other risk factors (Canadian Consensus Conference on Cholesterol, 1988; Toronto Working Group on Cholesterol Policy, 1989; Logan, 1990).

Need for a policy...

3.9 The scientific data base on lipids and heart disease is extensive; however, there are different interpretations of these data. For this reason, a policy is needed. The present consumer and commercial interests in the cholesterol issue do not allow for a moratorium on decision-making. There is evidence that the health care system is already beginning to feel the increased costs of managing hypercholesterolemia. It is safe to assume that laboratory and treatment costs will continue to increase. Adoption of a national strategy to guide health policy development in this area is a means of managing the problem and channelling the resources that are already being used in the most effective manner.

...of wide scope...

3.10 Throughout the consultations, the Working Group recognized the confusion and frustration of health professionals who deal with the cholesterol issue. There is a need for a Canadian policy on issues of public and professional education (uniformity of message), improvement of measurement of blood lipids, effective dietary strategies, evaluation and treatment guidelines and an intersectoral approach to marshal the wide array of resources needed to deal with this issue.

The Canadian Consensus Conference on Cholesterol ... a starting point...

3.11 A policy framework already exists. The Canadian Consensus Conference on Cholesterol concluded that programs should be implemented to reduce the average blood cholesterol in the population through a public health approach that would also address other risk factors for ischemic heart disease. The Conference gave guidance on priorities for the detection, evaluation and management of patients with elevated blood cholesterol. Consistent with its mandate, the Working Group has taken as a starting point for its analysis the recommendations of the Canadian Consensus Conference on Cholesterol (1988).

...consistent with other national and international guidelines...

3.12 It should be noted that the recommendations of the Canadian Consensus Conference on Cholesterol are generally consistent with those of similar comprehensive reviews carried out in the United States (National Cholesterol Education Program, 1988) and in Europe (European Atherosclerosis Society, 1987). In addition, the Working Group has examined carefully other positions and discussed the issue with representatives of other groups that have considered this matter (The Toronto Working Group on Cholesterol Policy, 1989; The Canadian Task Force on the Periodic Health Examination, Logan, 1989; the (U.S.) National Cholesterol Education Program). The Working Group recognizes that there is no single, ideal option and that a judicious mix of strategies will be necessary to deal with the cholesterol issue.

3.13 The Working Group is satisfied that a firm scientific base exists to support a public health policy. However, the biomedical knowledge base and the technological means for intervention in these issues are rapidly evolving. Based on the outcomes of the consultative process and on scientific advice available to it, the Working Group has endeavoured to identify an approach consistent with the recommendations of the Canadian Consensus Conference on Cholesterol which at the same time tries to take into account the recommendations of other Canadian reports.

A long-term approach... as resources permit...

3.14 The strategy framework proposed in this report is not intended to be short term. The perspective is long term and one which, over the next decade, will afford all Canadians the benefits of prevention and increased quality of life commensurate with judicious use of limited health care resources. For this reason, this report separates the analysis into two major parts: (1) discussion of the issues that lead to the identification of public health goals that would extend the benefits of prevention to all Canadians throughout the lifecycle, and (2) discussion of strategies or options that might be staged over a number of years to attain these public health goals. It is only sensible to expect that the implementation of the proposed strategies take place in the context of the priorities of the different provincial jurisdictions as resources permit, while taking into account the readiness of the health care system, the evolving nature of the science base, the need for broad ongoing consultation among different sectors and the short-term constraints on health care resources.

4. ISSUES AND GOALS

4.1 The potential for prevention

8,000,000 Canadians at risk...

4.1.1 Recent population surveys of cardiovascular disease risk carried out in a number of Canadian provinces (Provincial Heart Health Surveys, 1987-91) indicate that two in three adult Canadians have one or more of the major risk factors for ischemic heart disease (regular cigarette smoking, high blood pressure (diastolic equal to or greater than 90 mm Hg and/or on treatment) or elevated blood cholesterol (over 5.2 mmol/L)). Survey data indicate that 8,300,000 Canadian adults have blood cholesterol over the desirable level of 5.2 mmol/L, and among these, about 3 million are in the higher risk category (above 6.2 mmol/L) (Table 1).

Compounding of risks...

4.1.2 Blood cholesterol has been closely linked to the atherogenic process and is considered to be etiologically related to the development of ischemic heart disease (Davignon, 1977, 1983). Observational studies in many thousands of individuals show that the risk of ischemic heart disease death doubles as the level of blood cholesterol increases from 5.2 to 6.2 mmol/L. The risk doubles again for those who smoke and again doubles in the presence of elevated blood pressure (Stamler, 1986).

Drugs and medicalization...

4.1.3 Research studies have demonstrated that drug treatment for hypercholesterolemia can be beneficial in reducing the risk of developing ischemic heart disease as well as the progression of atherosclerotic lesions in patients with symptomatic heart disease (Havel, et al., 1989). However, the Working Group has been advised of the potential for undue and expensive medicalization. It has been pointed out that drugs may be an all too convenient path for both patients and physicians to follow in lowering blood cholesterol. Most drugs have the potential for side effects, which often do not manifest themselves for many years, and then only after many people have been treated with them (Grundy, 1986). Concern has also been expressed with the results of two of the drug trials which did not reduce all-cause mortality in the treated group relative to the control group (Lipids Research Clinics Program, 1984; Frick, et al., 1987). It should be noted that these trials were designed to evaluate only ischemic heart disease incidence, not all-cause mortality. However, in these trials there was an excess number of accidental deaths in the treated groups. While no

logical explanation exists for this observation, it should not be dismissed entirely as due to chance (Brett, 1989). The concern about medicalization is especially relevant for the management of elderly patients since for this group, diet therapy and physical exercise approaches to lowering blood cholesterol are not likely to be as effective (Palumbo, 1989).

The 2 for 1 rule...

4.1.4 Meta-analyses of trials of cholesterol-lowering drugs show that drugs may reduce blood cholesterol levels by 10% to 30%. Trials of diets, low in total fat and in saturated fat, demonstrate that 5% to 10% reductions in blood cholesterol are possible. Primary prevention trials in middle-aged men with elevated blood cholesterol levels (over 6.7 mmol/L) suggest that the risk of ischemic heart disease may be reduced by about 2% for every 1% reduction in the level of blood cholesterol (Marn and Marr, 1981; Tyroler, 1985, 1987; Lipids Research Clinics Program, 1984). Similar data from clinical trials on the benefits of reduction in women and in the elderly are not currently available.

The importance of moderate elevations...

4.1.5 The potential benefit from reduction of the blood cholesterol level for an individual with a moderate elevation is likely to be less than for an individual with a high level of blood cholesterol. However, in terms of the health of a community, the benefits from the reduction of blood cholesterol levels in individuals with moderate elevations are considerable: a small risk reduction in a large number of exposed people accounts for a large number of averted ischemic heart disease events (Rose, 1981).

Average lifestyle... the heart of the issue...

4.1.6 The average level of blood cholesterol among adult Canadians is estimated to be about 5.3 mmol/L (Provincial Heart Health Surveys, 1987-91). Elevated levels of blood cholesterol often co-exist with other risk factors for ischemic heart disease. These risk factors have their roots in similar patterns of lifestyle and conditions of daily living (e.g., diet, lack of physical activity, smoking, alcohol use). The following goals are proposed for the year 2000:

> ***Goal #1:*** **To reduce substantially the number of Canadians at risk due to elevated blood cholesterol and other risk factors for ischemic heart disease.**

> *Goal #2:* **To reduce the population average blood cholesterol for adult Canadians from the current 5.3 mmol/L to 4.9 mmol/L.**

4.1.7 The above goals support and are consistent with those of the report *Promoting Heart Health in Canada* (Federal Provincial Working Group on Cardiovascular Disease Prevention and Control, 1987) and the recommendations of the Canadian Consensus Conference on Cholesterol (1988).

4.2 *The central role of diet*

4.2.1 Diet is generally recognized as the pivotal lifestyle factor producing the current ischemic and cardiovascular epidemic in industrialized countries (Stamler, 1988). Diets rich in total fat, saturated fat, cholesterol and high in calories relative to energy expenditure as well as obesity appear central to the issue of mass hypercholesterolemia currently experienced in North America (Blackburn, 1979).

Nutrition recommendations for Canadians...

4.2.2 The Canadian Consensus Conference on Cholesterol (1988) recommended that comprehensive dietary guidelines for Canadians specify a reduction in the intake of total fat to about 30% of total energy intake with saturated fatty acids accounting for 10% or less. This has now been endorsed in the new Nutrition Recommendations, which also suggest that the cholesterol intake of the Canadian population be reduced (Department of National Health and Welfare, 1990a). The Nutrition Recommendations are intended for healthy individuals over the age of two years. The (U.S.) National Research Council's report on diet and health (1989), the population panel report of the National Cholesterol Education Program (1990) and the review of the European Atherosclerosis Society (1987) contain similar recommendations. In addition they propose restricting the intake of dietary cholesterol to fewer than 300 mg/day.

Changes in fat consumption...

4.2.3 Changes in dietary practices have been under way in Canada for the last 10 to 15 years. However, relative to dietary goals, the progress made in the reduction of total fat consumption has not been significant. From food disappearance data, total fat consumption appears to remain about 37% to 40% of energy intake. Currently, saturated fat consumption is esti-

mated to be about 13% of caloric intake. There has been a favorable shift towards the use of fats derived from predominantly unsaturated vegetable oils (Robbins, Robichon-Hunt, 1985). However, over 50% of all vegetable oils undergo hydrogenation (Beare-Rogers, 1990) a process which produces saturated and trans-unsaturated fatty acids found in shortenings and margarines. In view of the fact that only a few studies are available on the metabolic effects or fates of the trans-fatty acids, it is difficult to assess the health implications of the consumer shift towards vegetable oils (Grundy, et al., 1989a)

Saturated fat and dietary cholesterol...

4.2.4 The potential for dietary change to produce a reduction in the average blood cholesterol level of Canadians is quite significant. Diets rich in saturated fat and cholesterol reduce the number of LDL-receptors in the liver, which decrease the rate of removal of LDL-cholesterol from the circulation (Brown, Goldstein, 1986). It is recognized that in the average Canadian diet, saturated fat is a more important contributor to elevated blood cholesterol than is dietary cholesterol. However, the latter is not without importance. Dietary cholesterol appears to be an independent risk factor for ischemic heart disease (Shekelle et al., 1989). While increasing intake of cholesterol raises plasma LDL-cholesterol only modestly, this background intake of cholesterol is essential for the very marked effects of saturated fats (Dietschy, 1990). A reduction of saturated fat intake of two-thirds (from 18% to 6% calories from fat), for a person with a blood cholesterol of 5.2 mmol/L, should result in a fall of blood cholesterol of about 0.6 mmol/L; i.e., about a 10% reduction in blood cholesterol (Hegsted, 1986). By contrast, a 25% reduction in dietary cholesterol intake, from current levels of about 400-450 mg/day to 300 mg/day would result in a projected drop in blood cholesterol of about 0.2 mmol/L, or 3% to 5% for an individual in the neighborhood of 6.2 mmol/L (Christakis, 1988; Hegsted, 1986).

4.2.5 The Working Group was repeatedly apprised of the degree of confusion that surrounds the issue of cholesterol in the context of what constitutes a healthy diet. It is commonly accepted that the public information messages reaching the Canadian public on matters of dietary fat and dietary cholesterol originate mainly in the U.S. media. When Canadian, the source is usually the food industry. Health and nutrition professionals clearly indicate that consumers require specific, clear and practical information so that they may select a diet in accordance with dietary guidelines.

Practical dietary guidelines...

4.2.6 Recent Nutrition Recommendations from the Department of National Health and Welfare (1990a, 1990b) are a practical goal. They need to be translated to the public in plain terms and must be accompanied by a marketing environment that makes a healthy diet accessible and affordable, particularly for the more disadvantaged groups in our society. In addition, dietary guidelines must be sensitive to the fact that Canada is a multicultural country. The following goal is proposed for the year 2000.

> *Goal #3:* **To reduce average daily intake of total fat and saturated fat to 30% and 10% respectively of total calories.**

4.2.7 This goal is consistent with the recommendations of the Canadian Consensus Conference on Cholesterol (1988) and with the recent scientific review of the Department of National Health and Welfare (1990a).

4.2.8 In the interest of consistency with the recently released Guidelines for Healthy Eating (Department of National Health and Welfare, 1990b) the Working Group has not included in Goal #3 a recommendation for the general population to limit cholesterol intake. However, it considers that a limit of 300 mg/day is advisable for individuals with high elevations of blood cholesterol (6.2 mmol/L and over) and for those whose usual cholesterol intake is excessive. Accordingly, nutrition education programs should provide information to the public on the relevance of dietary cholesterol. Physicians and dieticians should take into account cholesterol intake and be prepared to provide advice, when appropriate, in interview and counselling settings.

4.3 *Children, adolescents and young adults*

Early onset of atherolsclerosis...

4.3.1 There is ample scientific evidence that control of lipids should not wait until the adult years. Atherosclerosis is a disease process that starts early in life (Enos, 1953; McNamara, 1971). Prospective studies have shown that school children who have high lipid levels during their early childhood years tend to retain higher than average lipid levels as teenagers and young adults (Freedman, 1985; Lauer, 1988). Elevated blood cholesterol levels have been shown to be correlated with an increased incidence of young adult ischemic artery disease

(Newman et al., 1986). Children in the upper 90th percentile (4.8 mmol/L) are regarded as being at significantly increased risk of ischemic heart disease when they reach adulthood (Canadian Consensus Conference on Cholesterol, 1988; National Cholesterol Education Program, 1988).

4.3.2 As is the case with adults, the average level of blood cholesterol for children in North America, and some Northern European countries is considerably higher than in Mediterranean countries such as Italy (Farinaro et al.,1986), where the mean values are 20% lower than in some Canadian populations (Vobecky and Vobecky, 1988).

Children and diet...

4.3.3 Diet is recognized as the most important environmental contributor to elevated blood cholesterol levels in populations with high rates of cardiovascular disease. Accordingly, recent nutrition recommendations propose that children over two years of age should be candidates for the same fat reduction or restriction as adults (Department of National Health and Welfare, 1990; National Research Council, 1989). Health promotion intervention studies to reduce the level of blood cholesterol in children have met with limited success (Puska, et al., 1982; Tell, Vellar 1987; Walter et al., 1988; Downey et al., 1987). However, this should not preclude the development and implementation of lifestyle education programs targeted to children and their families.

Limited data on children...

4.3.4 At the present time, it is not possible to state the extent of ischemic heart disease risk among Canadian children. No large scale comprehensive risk factor or nutrition surveys have been conducted in Canada. In addition, the risk associated with moderate elevations in factors such as blood pressure and blood cholesterol in children is not clear. Unhealthy lifestyle habits are acquired early in life. The smoking habit is often acquired in childhood and adolescence. Surveys of school children have identified deficits in knowledge and behaviour in the areas of diet, physical activity and weight control (Department of National Health and Welfare, 1986). It is necessary to take into account the ethical issues which might arise when youngsters are identified as being at risk. Thus, it is prudent to propose general healthy lifestyle programs. Programs for children which promote health, through appropriate nutrition, exercise and non-smoking should be appropriate to both family and school settings. Health education for children and adolescents needs to recognize the current concerns with overnutrition. To address these, programs must go beyond those of

traditional nutrition approaches which were aimed primarily at the prevention of undernutrition. The following goal is proposed for the year 2000:

> *Goal #4:* **To have Canadian children adopt healthy eating and physical activity habits, maintain a healthy body weight and avoid smoking.**

Young men and women...

4.3.5 Many young Canadian men and women are at increased risk of ischemic heart disease due to elevated blood cholesterol levels. Data from the Provincial Heart Health Surveys (1987-91) show that 21% of men and 17% of women ages 18-34 have moderately elevated blood cholesterol values between 5.2 and 6.2 mmol/L. For these same groups, the prevalence of highly elevated levels of blood cholesterol, over 6.2 mmol/L is 6% of men and 5% of women (Table 1).

Blood cholesterol rise with age...

4.3.6 An opportunity exists to prevent and control the progressive rise of blood cholesterol in young adults. In North American men and women, blood cholesterol levels increase by about 0.8 mmol/L between 25 to 35 years of age. Most of the rise is seen in LDL-cholesterol which is the atherogenic fraction (U.S. Department of Health and Human Services, 1980). A rise in average blood cholesterol levels in men after the age of 30 is related to diets rich in fat. Keys (1953, 1954) observed that there are populations in which it has been demonstrated that elevation of blood cholesterol is not a phenomenon associated with aging. Preventing the rise in blood cholesterol which occurs with age would be an effective way of lowering the average blood cholesterol of the population over time (even with minor or no reductions in current blood cholesterol levels).

5. STRATEGIES AND RECOMMENDATIONS

5.1 Inter- and intra-sectoral cooperation

A 10-year strategy...

5.1.1 A comprehensive approach to deal with the cholesterol issue requires a long-term perspective. Based on the experience with programs to control high blood pressure in Canada and in the U.S., the Working Group believes that a comprehensive approach to addressing this issue should take about ten years to develop and implement. Leadership and coordination are required to bring together the numerous resources and policy levers necessary to deal simultaneously with the main strategies that need to be brought to bear: identification of individuals at risk, public education, promotion of dietary change, evaluation and treatment, professional education and human resource issues, reliability of laboratory analysis of blood lipids and considerations of the impact on health care costs of alternative intervention strategies.

Diet is the cornerstone...

5.1.2 Dietary change is the cornerstone of the public health approach and the clear alternative to more expensive high-risk interventions. The creation of consumer environments supportive of healthy food choices involves working with different sectors and levels of government (regulatory, health promotion), voluntary health agencies, the food industry and consumers' associations.

Multifactorial approach...

5.1.3 In addition to concerns about cholesterol, effective public education on matters of diet and on cardiovascular disease prevention as a whole involves the reduction or control of other risk factors such as smoking, high blood pressure, physical inactivity and overweight. This requires marshalling the efforts of voluntary associations, such as the Heart and Stroke Foundations, and the Canadian Coalition for High Blood Pressure, as well as health promotion departments of different levels of governments and public health departments concerned with the promotion of healthy lifestyles.

Management guidelines...

5.1.4 Early identification, evaluation and treatment of individuals at higher risk requires that professional and medical associations be supported in the task of developing appropriate guidelines. This will reduce the confusion among health

professionals, will rationalize the priorities for identification of individuals at risk and will clarify the intensity of management and therapy. Leading partners are the Canadian Atherosclerosis Society, medical associations and sectors of government concerned with the control of health care costs. The drug industry is an important partner in promoting appropriate drug use.

Human resources...

5.1.5 Primary health care professionals are a key resource, already in place and currently dealing with the early identification, evaluation and management of individuals who are at high risk as well as those who require one-to-one counselling, management and periodic evaluation. However, there is a need to address the shortage of trained professionals, and to assist professional associations and educational institutions to enhance the knowledge, awareness and preventive-counselling skills of physicians, nurses, dieticians, pharmacists and others.

Reliable measurements...

5.1.6 The measurement of blood cholesterol and other lipids, namely HDL-cholesterol and triglycerides, needs to be made as accurate and precise as possible. This will prevent unnecessary economic and personal costs resulting from misclassification of individuals who may or may not be hyperlipidemic. Reliable measurement of lipids is essential if we are to realize the benefits of increased identification of individuals at risk and enable appropriate evaluation and management. This involves working with professional associations of clinical chemists, pathologists, laboratory organizations and provincial government laboratories to enhance internal and external quality control.

Coordination...

5.1.7 It is clear that someone has to lead. The Working Group is of the opinion that this role would be best assumed by provincial departments of health. In Canada, these departments have already adopted as a priority the prevention of cardiovascular disease in the context of the Federal-Provincial Heart Health Initiative. Provincial departments of health are poised to take the lead in coordination and in management of the cholesterol issue in the context of an integrated approach to prevention of cardiovascular disease. This leadership would include the establishment of effective coalitions with partners such as the Heart and Stroke Foundation.

5.1.8 The inter- and intra-sectoral approach should build on the numerous activities already under way within provincial jurisdictions. Leadership will bring about a degree of necessary coordination among these activities. Judicious policy and program development needs to recognize some precedence

relationships in the implementation of the different strategies. For example, public education and professional education should proceed in tandem; without delay, laboratories need to be encouraged and supported in implementing effective internal and external quality control procedures to increase the effectiveness of identifying hyperlipidemic individuals; access to dietary counselling should be ensured so as to help individuals reduce their blood cholesterol through dietary modification, rather than through drug use.

Policy to manage the issue...

5.1.9 A policy that addresses the cholesterol issue will begin to play in an environment where the public is as much or more sensitized to the issue than are the health professionals (Shucker, et al. 1987a, 1987 b). The demand for laboratory testing of lipids is steadily increasing in response to the recognition by the public and professionals of cholesterol as a risk factor; the demand for dietary counselling resources will inevitably increase. Lack of a policy and of coordinating action will not save resources. Significant health care resources are being increasingly utilized now to address blood cholesterol. The question is: do provincial jurisdictions wish to manage the issue, thereby rationalizing the use of resources now being spent? The Working Group recommends:

> *Recommendation #1:* **That provincial departments of health assume leadership in developing coalitions and coordinating policy and program development on the different aspects of the cholesterol issue in the context of heart health programs.**

5.2 *Public education and promotion of dietary change*

Low level of awareness...

5.2.1 A long-term strategy to reduce the premature onset of ischemic heart disease requires that all Canadians take action to reduce their risk factors. Awareness of risk factors for cardiovascular disease and how to reduce them is low: less than 60% of adults recognize smoking as a risk factor for coronary heart disease and less than 50% are aware of the other risk factors, of the relationship between dietary fat and heart disease and of the classes of foods whose consumption may reduce the level of blood cholesterol (e.g., consumption of low

fat dairy products recognized by 10% of adults) (Provincial Heart Health Surveys, 1987-91).

Confusion...

5.2.2 The cholesterol issue is additionally complicated by the fact that a substantial amount of confusion exists among consumers and health professionals. The Working Group was informed repeatedly through the consultation process that this confusion stems from a misunderstanding of the difference between dietary and blood cholesterol and from the role of saturated fat as a causative factor of elevated blood cholesterol. Much of the information available to the Canadian public today on the cholesterol issue stems from U.S. media and from commercial advertising. The Working Group has been told that Canadians lack practical, precise, complete and unbiased information on how to choose a diet that will help reduce and control the level of blood cholesterol.

Unbalanced messages...

5.2.3 Some educational nutrition information distributed in Canada by food producers often portrays the issue in an incomplete manner. Emphasis is often placed on a single dietary component, e.g., low content of dietary cholesterol, or low content of saturated fat or low content of fat (with no mention of saturated fat). It would be fair to assume that this confusion is, in part, due to the plethora and diversity of commercial messages which, inappropriately, tend to equate cholesterol-free products with healthy food. These commercial messages are not being counterbalanced by wide-reaching, credible, complete and consistent messages to help Canadians take action to lower their blood cholesterol. A partial and not always well-informed discussion in the public media of epidemiological issues surrounding interventional studies on diet and heart disease has exacerbated the confusion (Moore, 1989). The Working Group recommends:

> *Recommendation #2:* **That the federal, provincial and territorial departments of health, relevant voluntary agencies and professional associations develop consistent approaches that make Canadians aware of the meaning of elevated blood cholesterol as a risk factor for ischemic heart disease and advise them of actions they may take to control it.**

Program capability exists...

5.2.4 In the last few years, a number of Canadian communities have initiated heart health programs. Canadian provinces

have completed risk-factor surveys, have identified cardiovascular disease prevention as a priority for their public health systems and have initiated heart health programs in the context of the Federal Provincial Heart Health Initiative. The Heart and Stroke Foundation of Canada has introduced several national programs over the years addressing smoking, blood pressure, diet and exercise. An infrastructure already exists to promote public education and provide the supportive dietary advice needed to address the cholesterol issue and other risk factors. Effective partnerships among the community agencies is the key to ensuring that educational programs have a common message thereby reducing the consumer confusion surrounding the cholesterol issue. The Working Group recommends:

> *Recommendation #3:* **That the federal, provincial and territorial departments of health, voluntary health organizations and professional associations: (a) develop partnerships to deliver consistent public education messages on cholesterol; (b) integrate cholesterol messages for delivery in public information programs that address cardiovascular disease risk reduction in a multifactorial manner.**

5.2.5 There is a broad consensus that a dietary strategy focusing on lowering the consumption of fat, saturated fat and (although of lesser importance) dietary cholesterol is the cornerstone that will bring about reduced levels of cholesterol in the population at large (Stamler, 1979; European Atherosclerosis Society, 1987; Canadian Consensus Conference on Cholesterol, 1988; National Research Council, 1989; National Cholesterol Education Program, 1990; Department of National Health and Welfare, 1990a). Dietary patterns are deeply entrenched in culture and largely determined by food availability and price. Consumers' knowledge of the nutrient content of foods is an important factor in the ability to select a healthy diet. Thus, a long-term dietary strategy to deal with the cholesterol issue requires a dramatic and substantial shift in societal attitudes and behaviour patterns with respect to eating habits. Accomplishing this necessitates a supportive consumer environment in terms of appropriate nutritional information as well as availability and affordability of healthy food to facilitate healthy choices.

5-10% reduction in average blood cholesterol possible...

5.2.6 The Scientific Review Committee, charged by the Department of National Health and Welfare with the review of nutrition recommendations for Canadians, concluded that a mean reduction of fat intake to 30% of total calories, of saturated fat to 10% and a reduction of cholesterol intake are indicated for the Canadian population at large, two years old and over. These recommendations parallel those of the Canadian Consensus Conference on Cholesterol (1988) and the review of the (U.S.) National Research Council (1989). If implemented by the majority of Canadians, these recommendations would significantly contribute to attaining the goal of a population average blood cholesterol level of 4.90 mmol/L from the current average of about 5.30 mmol/L. More specifically, based on predictive equations linking blood cholesterol response to dietary fats and dietary cholesterol (Keys et al., 1965; Hegsted et al., 1965; Hegsted, 1986) and the extent of their applicability to free living populations (Mann, 1977; Food and Nutrition Board, 1980; National Diet-Heart Study Research Group, 1968), the Working Group has concluded that adoption by Canadians of the Nutrition Recommendations of the Scientific Review Committee, including reduction of dietary cholesterol intake, will result in a decrease of average blood cholesterol level between 5% and 10%. Adherence to the Nutrition Recommendations should help Canadians maintain a healthy body weight and possibly contribute to the prevention of some common types of cancers and other chronic conditions.

Specific nutrition education goals...

5.2.7 The Communications and Implementation Committee commissioned by the Department of National Health and Welfare to develop consumer advice and implementation strategies for the Nutrition Recommendations has prepared guidelines for healthy eating (Department of National Health and Welfare, 1990b). The Working Group considers it important that, as part of the process of developing the strategies, the federal, provincial and territorial departments of health and voluntary health organizations jointly develop specific goals for consumer education, for increasing the availability of less fatty products at points of sale and for ensuring that appropriate information is given to consumers. This will permit them to select a healthy diet that conforms to the Nutrition Recommendations and determine the extent to which they are complying with those recommendations.

The public and cholesterol...

5.2.8 Since the previous set of Nutrition Recommendations was released by the Department of National Health and Welfare (1977), the decrease in the mean total fat consumption of

Canadians, estimated from disappearance figures, has been marginal (Robbins and Robichon-Hunt, 1986). In designing future nutritional education concepts and programs to promote the new Nutrition Recommendations, consideration should be given to providing specific information in the areas of fats and cholesterol, where much of the confusion lies. This would be in addition to generalized nutrition information on healthy eating.

The level of public awareness of the word "cholesterol" is extremely high. The Working Group has been advised that it is an area where the public demands information. Neither health professionals nor nutrition education programs can afford to ignore this demand; if they do, informing the Canadian public about the cholesterol issue will be left to commercial interests or to U.S. messages. The Working Group endorses the recommendations of the Scientific Review Committee and those of the Communications and Implementation Committee (Department of National Health and Welfare, 1990a, 1990b) with one specific addition: that of informing the public about cholesterol. It cannot be ignored. The Working Group recommends:

> ***Recommendation #4:*** **That the federal, provincial and territorial departments of health, voluntary health agencies and professional organizations promote Canada's *Guidelines for Healthy Eating*, and in addition, provide the public with specific, clear and practical information to reduce the consumption of total fat and saturated fat.**

Current nutrition information and programs...

5.2.9 Nutrition information is available from numerous sources in Canada. *The Guidelines on Healthy Eating* (Department of National Health and Welfare, 1990b) provides general information on healthy dietary practices and is distributed widely to the public and throughout the school system. Provincial health departments also produce general nutrition information. The Heart and Stroke Foundation of Canada issued Nutrition Recommendations in 1988, followed up by the commercially distributed *Lighthearted Cookbook* (Lindsay, 1989), modules for cooking classes and the "Heart Smart" cooking course and restaurant program (Lauzon, 1990). The food industry (meat, dairy products and eggs) makes educational materials available to the public and to health professionals.

5.2.10 Some public health units within provincial and territorial departments of health are initiating, in collaboration with the private sector and voluntary health agencies, heart health programs which incorporate a nutrition component (e.g., "Mieux Vivre," Departement de santé communautaire du Lakeshore, Paquette, 1989; "A Change of Heart," East York Health Unit, Wallace, 1990). In Ontario, nutrition components are part of the mandatory health programs and services that are implemented by public health units under the provisions of the 1985 Health Protection Act. The Nutrition Branch of the British Columbia Ministry of Health has nutrition education components which actively support community based programs concerned with the promotion of healthy lifestyles (Carrow, Stovel, 1989). If properly evaluated, these programs may serve as models to other jurisdictions.

Dietary counselling for high-risk individuals...

5.2.11 With increasing numbers of Canadians being identified as having elevated blood cholesterol, the issue arises as to the most practical manner in which required nutrition information may be provided to those at increased risk. General nutrition information will be beneficial for everyone in the population, including those at high risk. However, to obtain significant dietary change in those at high risk, individualized or small group dietary advice may be necessary. This usually requires assessment of individual dietary patterns. To be effective, advice for change needs to be sensitive to the tastes and to the cultural and social situation of the individual or groups in question.

Point-of-purchase information...

5.2.12 The public requires supportive environments which reinforce their decision to adopt and maintain healthy lifestyles. The promotion of dietary change requires that consumers be able to exercise healthy food choices easily. Point-of-purchase nutrition information is an effective way to promote the education message (Battista, Potvin, 1988; Light et al., 1989). The 1988 amendments to the Food and Drugs Act removed a number of restrictions on nutrient declarations and changed the manner of nutrient declarations so as to be consistent with the *Guidelines on Nutrition Labelling* (Department of National Health and Welfare and Department of Consumer and Corporate Affairs, 1988). The Guidelines provide for standardization of the content and format of nutrition labelling. Information on poly-, mono- and on saturated fatty acids and cholesterol may be given under the fat content on the label, provided that the contents for the four constituents are displayed. This information is provided on a per-serving basis.

Nutrition labelling...

5.2.13 Currently, the nutrition labelling scheme is voluntary. The U.S. experience is an indication of what may develop in Canada. It is worth noting that in the U.S., after 15 years of operation, only 55% of the total dollar value of packaged foods is covered by nutrition labelling (Food and Drug Administration, 1986). There is legislation pending in the U.S. Congress that would make nutrition labelling mandatory. It is important to monitor the utilization of nutrition labelling in Canada. Nutrition labelling is potentially an effective way to empower the consumer with information which can be used to help him/her comply with the Nutrition Recommendations. There is a need to develop innovative approaches in the use of nutrition labelling, so that individuals may be able, with relative ease, to relate information provided on the label to the Nutrition Recommendations for Canadians (Department of National Health and Welfare 1990a, 1990b). The Working Group recommends:

> *Recommendation #5:* **That the Department of National Health and Welfare monitor nutrition labelling by the food industry; that it implement a program to educate consumers in the use of nutrition labelling and that it evaluate nutrition labelling within five years.**

Health claims...

5.2.14 Regulations pertaining to health claims are a much-debated topic in the context of heart health and nutrition education. It is of concern that health claims may inappropriately extol the nutritional value of some foods deemed to contain (or to lack) food constituents beneficial (or deleterious) to cardiovascular risk. Subsection 3(1) of the Food and Drugs Act states that "no person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the disease, disorders or abnormal physical states mentioned in Schedule A" (this Schedule includes heart disease, hypertension and diabetes). The Food and Drugs Act provision concerning health claims offers consumers much needed protection against inappropriate claims.

An intersectorial consortium...

5.2.15 The Working Group has been made aware that it might be desirable to examine the extent to which the Food and Drugs Act might accommodate the provision by health agencies of dietary information to the public in retail establishments. An ad hoc consortium of voluntary health organizations, food industry representatives, food distributors and government

agencies are currently discussing with the regulatory authorities in the Department of National Health and Welfare the development of generic guidelines. This should assist the delivery of health information to the public in a manner consistent with the requirements of the Food and Drugs Act. Pending the continuing dialogue with the aforementioned consortium, the Working Group considers that a recommendation on the issue of health claims now would be premature.

Nutrition information from industry...

5.2.16 Throughout the consultations, the role of the food industry in providing nutrition information to the public is well understood. The Working Group was advised that industry-generated nutrition information is not likely to provide the consumer with a straight-forward, balanced message on issues such as fat, saturated fat and cholesterol. Given the nature of advertising, it is normal to expect that food industry-generated nutrition information will aim to present a product in the best light based on its nutrient composition.

Nutrition policy for agriculture...

5.2.17 Policies and regulations designed to make healthy foods available are a necessary complementary step to public education and the provision of nutrition information to the consumer. The Department of Agriculture has developed a Nutrition Policy for Agriculture, the aim of which is to "work with producers, the food industry and consumers to assure a dependable supply of safe, nutritious food at reasonable prices to consumers, and equitable returns to producers and processors" (Lloyd, 1988). Grading standards can be effective in making available products that are more desirable in terms of the new dietary guidelines. Changes in grading systems to reward leanness instead of fat constitute financial incentives which have led to a decrease in carcass fat levels (Jones, 1989).

Grading standards...

5.2.18 The Communications and Implementation Committee for the Nutrition Recommendations has recommended that "appropriate changes be made to the Canadian Agriculture Products Act to allow for development of low-fat, standardized dairy and meat products" (Department of National Health and Welfare, 1990). Dairy products is one area in which gains to reduce fat content might be made. Currently, producers are reimbursed according to the fat content of the milk. This encourages the production and sale of whole milk and butter instead of low-fat dairy products. The Working Group has been advised that alternative standards are being studied which would take into account, in addition to butter fat, protein

content and other solids in the reimbursement formula (Horgan, 1989).

Economic impact of dietary change...

5.2.19 The above discussion highlights the value of the intersectoral approach for bringing about dietary change. It is important that advice to the public on the nutritional properties of food products be based on scientific fact. Proper regard must be given to the impact that dietary change may cause on the economic structure of the food industry (Lloyd, 1988).

Provincial nutrition policies...

5.2.20 To deal effectively with the cholesterol issue, it is important that all relevant partners in the public and private sectors develop policies that support implementation of the Nutrition Recommendations. To be effective, policies need to be fitted to the social and economic ecology of different regions of Canada and take into account the realities of the local economy. Policies are needed at different levels of government, but it is the view of the Working Group that these policies would be most effectively developed and implemented at the provincial level. The Working Group recommends:

> *Recommendation #6:* **That provincial and territorial departments of health develop nutrition policies for their own jurisdictions, which are sensitive to the needs of different cultural and socio-economic groups and which suit their local economies.**

5.2.21 Current national information concerning what Canadians eat is lacking. The Nutrition Canada Survey was carried out in 1970-71 (Department of National Health and Welfare, 1973). Up-to-date information on the nutrient intake of Canadians and on the sources of dietary intake is required to assess the extent to which Canadians are following the Nutrition Recommendations and to plan and evaluate nutrition programs. Provinces participating in the Federal Provincial Heart Health Initiative are now beginning to carry out provincial surveys of nutrition supported by the Health Protection Branch of the Department of National Health and Welfare (Beare-Rogers, 1989; Stachenko, 1989, Lessard, 1989; MacLean, 1989). Such provincial surveys should follow a standardized protocol so that a national nutritional picture may emerge. The Working Group recommends:

> *Recommendation #7:* **That provincial and territorial departments of health, in collaboration with the Department of National Health and Welfare, conduct standardized nutrition surveys in their jurisdictions.**

5.3 *Identification, evaluation and treatment*

Who should be tested...

5.3.1 Because of the importance of cholesterol in and of itself as a risk factor, the U.S. Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults recommended that all adults have their cholesterol measured (National Cholesterol Education Program, 1988). Other guidelines have qualified cholesterol testing by requiring the presence of other risk factors. These include smoking, high blood pressure, diabetes, obesity and a family history of hypercholesterolemia or early onset of ischemic heart disease as well as patients with renal failure or ischemic heart disease.

Presence of other risk factors...

5.3.2 The Canadian Consensus Conference on Cholesterol (1988) and the Canadian Lipoprotein Conference Ad Hoc Committee on Guidelines for Dyslipoproteinemias (1990) have proposed testing of adults when other risk factors are present. The Canadian Cholesterol Consensus Conference recommended that: "determination of risk factors be considered a priority for the following groups of patients: a) Patients known to have coronary heart disease. b) Patients with a family history of hyperlipidemia or early onset of coronary heart disease (heart attack in a parent, grandparent, brother or sister before age 60 years). c) Patients with hypertension, diabetes mellitus, renal failure or obesity, especially abdominal obesity [The Working Group has been advised that smoking as a risk factor was inadvertently omitted in the list of factors]. As resources permit, determination of lipid risk factors should become part of the periodic health examination for all adult Canadians. Priority should be given to those with other risk factors".

Adult males...

5.3.3 According to recommendations of the U.S. Preventive Services Task Force (1989), the preliminary report of the Canadian Task Force on the Periodic Health Examination (1990) and the Toronto Working Group on Cholesterol Policy (1989) adult males in specified age groups with or without risk factors are eligible for priority testing. The guidelines of the British Co-

lumbia and Yukon Heart Foundation (1988) and of the Saskatchewan Heart and Stroke Foundation (1988) recommend testing for both men and women in middle-aged groups regardless of the presence of other risk factors.

Conflicting recommendations...

5.3.4 There is variance among the above guidelines concerning issues of evaluation and management, including: frequency of measurement, levels at which treatment actions are taken, type of blood lipoprotein tests recommended as follow up to initial identification, degree to which the presence of other risk factors governs intensity of management and the criteria for entry into drug treatment. Most guidelines recommend that some dietary advice, or therapy in the case of other risk factors, be given to an individual whose blood cholesterol is between 5.2 and 6.2 mmol/L. Guidelines prepared by a Working Group of the Quebec Heart and Stroke Foundation (1989) emphasize the importance of diet as the first line of treatment and the need for a multifactorial approach to risk reduction.

> *Recommendation #8:* **That the Department of National Health and Welfare support the Canadian Atherosclerosis Society and other relevant professional organizations in the development of guidelines for the evaluation and treatment of hypercholesterolemia in adults.**

5.4 *Professional education and human resources*

5.4.1 The Working Group was repeatedly made aware of the less than optimal knowledge and skills of health professionals to deal effectively with reducing ischemic heart disease risk. The potential role of these professionals in reinforcing public education efforts is considerable.

Physicians...

5.4.2 About 75% of Canadians see a physician every year (Statistics Canada, Department of National Health and Welfare, 1981). Physicians are well-positioned to support behaviour and lifestyle change for cardiovascular disease risk reduction (Elford, Weo, 1988; Elford et al., 1989). With respect to smoking, physicians can have a considerable impact on behaviour (Cohen et al., 1989). Surveys point to a great readi-

ness of doctors to identify and to manage patients for hypercholesterolemia (Reeder et al., 1989; Battista et al., 1989); to play an important role in educating patients about nutrition (Kelly, Joffres, 1990); and in providing dietary counselling (Langner, 1989).

Factors that influence preventive practices...

5.4.3 Traditionally, curricula for physicians have focused on the diagnosis and treatment of disease. Studies of physicians' perceptions regarding their role in cardiovascular disease prevention indicate a need not only for knowledge, but also for skills that are critical to the task, e.g., enhancing patient compliance and bringing about behavioural change (Mann, Putnam, 1989, 1990). Other factors perceived by physicians as affecting the amount of cardiovascular disease prevention possible in their practices include: lack of recognition of preventive activities in fee schedules (Lawrence, Battista, 1987); lack of knowledge of available community resources such as dietitians and self-help groups (Mann, 1989; Mann, Putnam, 1990); lack of patient education materials (Kelly, Joffres, 1990); and a lack of professional resources that translate the evidence from research to practical approaches in the physician's office (Elford, Yeo, 1988). Due to the multiplicity of guidelines for the identification, evaluation and management of hypercholesterolemia, physicians are confused as to how the issue should be handled. National guidelines are needed and must be incorporated into professional education efforts in order for them to become known, understood and used effectively in practice (Mann, 1989).

Models for professional education...

5.4.4 A number of medical schools in Canada (e.g., Calgary, McMaster, Dalhousie and Saskatchewan) are developing and evaluating training models for physicians in the area of cardiovascular disease risk factors (Mann, 1989). The models involve self-learning modules and workshops to assess patients' risk, behavioural goal-setting and techniques for counselling in areas such as smoking cessation and exercise. An interesting program brought to the attention of the Working Group is the (U.S.) "Preventive Cardiology Academic Award" designed to encourage the development of high-quality preventive cardiology curricula in schools of medicine and to provide opportunities to medical students to learn the principles and practice of preventive cardiology. As part of the program, core curricular guidelines have been prepared. Counselling skills are taught through role playing and with the help of interactive computer programs (Stone, 1989).

Continuing medical education...

5.4.5 Continuing medical education provides an appropriate venue for the professional education of physicians. It is provided through a variety of channels including; university departments, national and provincial medical associations, voluntary agencies, professional associations and pharmaceutical companies. The medical associations disseminate information about continuing medical education programs but they do not involve themselves in program development, La Fédération de Medecins Omnipraticiens du Québec being an exception. The Heart and Stroke Foundation of Canada and some of its provincial affiliates such as Quebec, Ontario and Nova Scotia play a significant role in the development and administration of continuing medical education programs of cardiovascular disease prevention (Mann, 1989).

Nurses...

5.4.6 Community health and occupational health nurses can play a key role as educators in delivering the cardiovascular disease prevention message. Public health nurses have a long history of involvement in nutrition education, primarily in the maternal and child health area. Thus far, they have had a limited involvement in the area of prevention of chronic disease (Sabry et al., 1987). The Conseil canadien des infirmières cardiovasculaires have expressed to the Working Group an interest in participating in prevention and educational activities. If the public health system is to utilize the potential of nurses in the prevention of cardiovascular disease, training in nutrition and the evaluation and management of hypercholesterolemia and other risk factors is required.

Continuing nursing education...

5.4.7 Continuing education for nurses is available from sources such as community colleges and provincial public health units. Thus far, university schools of nursing and nursing associations have played a limited role in continuing education (Mann, 1989). National and provincial nursing associations are involved in assisting the specialty groups of nurses (e.g., occupational, cardiovascular, family practice) with their educational activities.

Nutritionists...

5.4.8 Nutritionists and dietitians have a key role to play in the implementation of a dietary strategy to deal with the public education and individual counselling aspects of the cholesterol issue. It is important that the continuing education needs of these professional groups be met. The Working Group recommends:

> *Recommendation #9:* **That the professional associations of physicians, nurses and dietitians, the provincial and territorial departments of health and educational institutions develop curricula and continuing education programs to enhance knowledge and skills for identification, evaluation and management of hypercholesterolemia and other ischemic heart disease risk factors.**

Shortage of dietitians...

5.4.9 Presently, the majority of dietitians function primarily in a hospital setting and see high-risk individuals on referral by a physician and deal with specific disease entities such as diabetes, obesity and gastro-intestinal and lipid disorders. A lesser number function in community, industry and private settings. Most provinces have a shortage of professional dietitians as attested to by accounts of extensive waiting lists for dietary counselling. In Manitoba, a survey of hospital out-patient dietetic services indicated that services are often overtaxed and long waiting lists exist. In rural areas, registered dietitians have little time for counselling. While it has been pointed out that consultation with a dietitian in private practice is an alternative, many people may not be able to cover all or part of the dietitian's fee (Working Committee of the Manitoba Association of Registered Dieticians, 1989).

Lack of internships...

5.4.10 The Working Group has been told that the provision of nutrition information at the community level is hampered by the lack of properly trained community health dietitians. There is a limited number of dietitian internships both at the clinic and at the community levels. This seems to be particularly so in provinces other than Quebec (about four community health dietitians graduated from internships in Canadian provinces other than Quebec in 1988 (Sharpe, 1989)). In Quebec all graduates of dietetics receive, within their program of studies, a one-year internship which includes practica at the clinical and community health levels (Lachance, 1989). The Working Group believes that the Quebec approach to the training of dietitians could serve as a model to other provincial jurisdictions to alleviate the shortage of these professionals. The shortage of dietitians will only be exacerbated by the expected increase in demand as professionals and the public respond to the cholesterol issue. The Working Group recommends:

> ***Recommendation #10:*** **That provincial and territorial departments of health, in consultation with professional associations and educational institutions ensure sufficient community and clinical dietitian internships are available to support nutrition education programs and the demand for dietary counselling.**

Multidisciplinary approaches...

5.4.11 Cardiovascular disease prevention requires interventions at different levels in the community and involves the skills and knowledge of a variety of health professionals. The Working Group has noticed an insufficient appreciation among the different health professions for the respective contribution that each profession can make to the resolution of the cholesterol issue. It would be appropriate to develop and evaluate multidisciplinary approaches to continuing professional education which would promote the prevention and control of hypercholesterolemia in particular, but also cardiovascular disease generally. There is a significant opportunity for voluntary associations such as the Heart and Stroke Foundation of Canada, to sponsor continuing educational activities designed to bring all health professional groups together to acquire knowledge and skills around the issue of cardiovascular disease prevention. This would reinforce the thrust towards the multidisciplinary approach to cardiovascular disease prevention.

Partnerships...

5.4.12 Multidisciplinary collaboration may be enhanced by fostering partnerships among primary care professionals, public health departments and voluntary health organizations and encouraging their joint participation in health promotion campaigns at the community level. The Working Group recommends:

> ***Recommendation #11:*** **That educational institutions, professional associations and voluntary health agencies support continuing education activities that reinforce multidisciplinary approaches to cardiovascular disease prevention.**

5.5 *Measurement of blood cholesterol and other lipids*

5.5.1 Precise and accurate lipid measurements are required to detect individuals at risk of coronary heart disease, assess a person's risk of coronary heart disease and to prescribe and monitor treatment. Epidemiological studies of the distribution of lipids in populations require precise and accurate measures to permit comparability among studies, within studies over time and to provide a valid assessment of population risk.

Precision...

5.5.2 "Precision," or day-to-day reproducibility of the value of a blood specimen, assesses the amount of random error and is expressed by the coefficient of variation (standard deviation of a set of values divided by the average). To illustrate the meaning of precision, for a laboratory analyzing a specimen with a true value of 5.2 mmol/L, and a coefficient of variation of 10%, it might be expected that about one-third of the replicate measurements, in that same specimen, would fall outside the range of 4.8 to 5.7 mmol/L. This level of precision would make it difficult to detect changes in a patient undergoing diet therapy, for whom a 10% reduction in blood cholesterol might be a reasonable outcome.

Accuracy...

5.5.3 Accuracy assesses the amount of bias, that is the degree of agreement of a measurement with an accepted reference value. An inaccurate analytical method would consistently yield values above or below the reference value, independent of the random errors, depending on whether the bias is positive or negative. Bias or inaccuracy is measured as the difference between the measurement or average of measurements obtained for a given reference specimen (M) and the true value of the reference specimen (T), divided by the true value ((M-T)/T).

Bias...

5.5.4 Repeated analysis of the same specimen does not reduce the bias resulting from an inaccurate measurement system. Analysis of blood lipids can be rendered accurate only by the use of appropriate reference materials for calibration and monitoring of the analytical process.

Misclassification of individuals...

5.5.5 The mounting numbers of lipid analyses being performed in Canadian laboratories in the last few years, and the increasing number of Canadians who will be found to be at some degree of risk make it critical to enhance reliability of blood lipid measurement. Not to do so will result in the inap-

propriate classification of thousands of individuals as being at risk, and alternatively, the failure to detect individuals who are at risk due to truly elevated blood cholesterol. The human and economic consequences of misclassification of such large numbers of individuals would be considerable.

Goals for precision and accuracy...

5.5.6 To ensure a reasonable likelihood of correct classification, the Canadian Society of Clinical Chemists (1988) has recommended a 3% coefficient of variation as a goal for precision for blood cholesterol; for triglycerides, HDL- and LDL-cholesterol a 5% coefficient of variation. Similarly the goal for accuracy, expressed as maximum bias from the target value, should be 5% for the four lipids. The National Cholesterol Education Program has set comparable goals for precision and accuracy for total cholesterol testing in the U.S.(Laboratory Standardization Panel of the National Cholesterol Education Program, 1988).

Current laboratory performance...

5.5.7 Many of the major laboratories carrying out analysis of blood cholesterol are already within or close to the limits for accuracy and precision for total cholesterol. With respect to accuracy, national (Hynie, 1989) and provincial surveys (Lays and Breckenridge, 1988; Patten, Forest, 1990) would indicate that more than 50% of laboratories have a deviation of less than 5% from the reference values. With respect to precision, about 50% of laboratories participating in provincial surveys in Ontario and Quebec have a coefficient of variation less than 4% (Canadian Society for Clinical Chemists, 1988; Patten, Connelly, 1988; Patten, Forest, 1990). By and large, precision tends to be less of a problem than accuracy. Data indicate that laboratory performance in both accuracy and precision is improving (Patten, Connelly, 1988). The combination of bias and lack of precision, added to other preanalytical sources of variation (biological, behavioural, collection and handling of specimens) (Cooper, 1988), can result in substantial error in a single analysis. It is for this reason that replicate determinations are needed before an individual can be classified correctly by cholesterol level.

Precision and accuracy for fractions...

5.5.8 Most laboratories performing blood cholesterol analyses also perform triglyceride (TG) analysis and about 40% perform HDL-cholesterol testing. The lack of precision of triglyceride analysis exceeds that of blood cholesterol. With respect to HDL-Cholesterol, there are insufficient data to quantify the accuracy and precision of testing this lipid fraction. However, the more complicated methodology required to

measure HDL-cholesterol would indicate that its measurement is less precise and accurate than that of blood cholesterol. This applies also to the LDL-Cholesterol which is not measured directly, but is a value derived by formula from the total blood cholesterol, triglycerides and the HDL-Cholesterol (LDL=TC-(HDL+0.46xTG)). Reliable measurement of triglycerides and HDL-Cholesterol must be made since the LDL-cholesterol value is regarded as the key indicator in the decision to intervene with cholesterol lowering therapy (Patten, Forest, 1990).

Increasing volume of analyses...

5.5.9 The number of blood cholesterol, triglyceride and HDL-cholesterol analyses requested has risen sharply in the last five years. Data from some Canadian provinces (British Columbia, Manitoba, Ontario, Quebec, Newfoundland) (Patten, Forest, 1989) and from Saskatchewan (West, 1990) indicate that, depending on the type (provincial, medical care institution, private) and geographical location of the laboratory, the annual rate of increase in the number of blood cholesterol determinations has been 10% to 40%, for HDL-cholesterol 20% to 125% and for triglycerides 10% to 25% (Patten, Forrest, 1990).

The matrix effect...

5.5.10 Most existing routine laboratory methods are capable of performing with acceptable accuracy provided that calibrating materials are correctly standardized. Calibrators are provided by manufacturers of analytical systems in the form of lyophilized preparations which do not mimic necessarily the behaviour of the analytical system when a sample of fresh human serum is used. An analytical system may be calibrated with respect to the calibrating material but the performance vis à vis analysis of actual blood samples may yield inaccurate values. This is referred to as the matrix effect. The fact that many manufacturers are already providing calibrators standardized to a reference material to account for matrix effects should begin to improve the accuracy of blood cholesterol analyses. However, laboratories using instruments from one manufacturer and calibrators from another cannot have this assurance. These laboratories (about 30% of all laboratories) need to undertake a program of standardization with a reference laboratory to establish a calibrator value that assures correct patient results (Patten, Forest, 1990).

Internal quality control...

5.5.11 The reliability of lipid measurements generated by a laboratory can be ascertained and improved upon by external and internal quality control procedures. Internal quality control programs are run by individual laboratories to ensure day-to-day repeatability (precision) of the results produced by

their instruments. In general, the commercial lyophilized blood specimens used allow a reasonable evaluation of precision, but not necessarily of accuracy. There are insufficient data available to the Working Group to evaluate the performance of Canadian laboratories on their internal quality control. From the experience of the Province of Ontario Medical Association Laboratory Proficiency Testing Program (LPTP) it would appear that many laboratories do not have a proper understanding of the operation of quality control programs (Patten, Forest, 1990). The difficulties of using certain types of commercial calibrators to calibrate their analytical systems for lipid measurement have been noted by the Laboratory Standardization Panel of the (U.S.) National Cholesterol Education Program (1988).

External quality control...

5.5.12 Checks of the accuracy of lipid values generated by laboratories require their participation in programs which provide reference materials for testing and to which known values of cholesterol or of a fraction thereof have been assigned. "Proficiency Testing" generally implies an external quality control program in which a government or other agency supplies material to laboratories for blind analysis, with the results analyzed centrally. They may have an educational component, as is the case with the LPTP of the Ontario Medical Association and the program of the Societé québecoise de biochimie clinique. Commercial interlaboratory survey programs provide external quality control to many Canadian laboratories. Two major systems used in Canada are the College of American Pathologists (CAP) surveys and the Wellcome Diagnostics Clinical Chemistry Quality Assessment Programme. Participation in some type of proficiency testing programs is mandatory in British Columbia, Alberta, Ontario and Nova Scotia. In the other provinces participation is voluntary. In Quebec, 70% of the laboratories participate in the voluntary program of the Societé quebecoise de biochimie clinique (Patten, Forest, 1990). As stated above (5.5.11), commercial lyophilized blood specimens used in proficiency testing programs do not necessarily allow assessment of accuracy.

Lack of reference materials...

5.5.13 A key barrier to obtaining satisfactory accuracy for blood cholesterol analysis in most Canadian laboratories is the lack of appropriate reference materials for calibration and for external quality control (proficiency testing programs). Currently available pools of reference material (human blood samples), with cholesterol values assigned by a reference method, are in short supply in Canada. In the past, reference

sample specimens have been available from pools maintained by the U.S. National Institute of Standards and Technology (formerly the National Bureau of Standards) and by the Center for Disease Control in Atlanta. There are no reference materials for HDL-cholesterol testing at all (Patten, Forest, 1990).

Need for reference laboratories...

5.5.14 The Working Group has been advised that the suitability of currently used lyophilized materials for calibration or for use in external quality control programs is questionable. It seems desirable that reference materials be available from Canadian sources. This would imply establishing and supporting one or more lipid reference laboratories. The role of such laboratories would be to provide reference materials as calibrators as well as standardized internal and external quality control materials, to supply reference measurements on individual human serum specimens to manufacturers developing or refining cholesterol methods, and to assign cholesterol values to all commercially prepared lots of quality control materials, according to an established sampling protocol. There are a number of laboratories in Canada with the research capability to become reference laboratories. The Core Lipid Laboratory in Toronto is currently standardized to the Lipid Research Clinics laboratory in the Center for Disease Control (Atlanta, U.S.). The Cholesterol Research Foundation in Vancouver is in the process of qualifying as a reference laboratory and has entered a collaborative program with the Center for Disease Control in Atlanta (Seccombe, 1989). Several other provinces have laboratories with the expertise to become reference laboratories. The Working Group recommends:

> *Recommendation #12:* **That the Department of National Health and Welfare and the provincial and territorial departments of health examine the feasibility of establishing and supporting one or more reference laboratories which would standardize clinical laboratories and would produce the reference materials required both for proficiency testing programs and the quality control of laboratory analysis of blood lipids.**

Quality control: a good investment...

5.5.15 The Working Group recognizes that there will be costs associated with enhanced internal and external quality control for the testing of blood lipids, but believes it to be a wise investment of resources. The improved precision and accuracy of blood lipid determinations would significantly reduce the

number of patients who are currently misclassified as requiring medical follow up and management. Similarly the number of individuals who require management, but who are erroneously classified as normal, would be offered evaluation and treatment. Improved precision and accuracy of blood lipid testing will also reduce the amount of repeat testing that is now necessary to ascertain adequately the patient's lipid profile. The Working Group recommends:

> ***Recommendation #13:*** **That provincial and territorial departments of health ensure the reliability of analysis of blood lipids by requiring laboratories to participate in internal and external quality control programs.**

Reporting of results to physicians...

5.5.16 Many laboratories, when reporting results to physicians, classify as "normal" the range between the 2.5th and 97.5th percentiles of the population (Hynie, 1989; Patten and Forest, 1990). This practice assumes that what is statistically normal is also the norm on which to judge acceptable (normal) blood lipid status. In Canada, where the average blood cholesterol is above healthy standards this criterion for reporting "normal" values to physicians gives them inappropriate information and it is a source of confusion. It would be desirable that Canadian laboratories adopt a unique set of cut-off points to report normal ranges to physicians. Presently this is hindered by the increasing number of conflicting recommendations for evaluation and treatment that are now appearing. The Working Group recommends:

> ***Recommendation #14:*** **That provincial and territorial departments of health and professional associations ensure that clinical laboratories, when reporting the results of blood lipid tests to physicians, classify individuals according to the established cut-off points recommended by the Canadian Consensus Conference on Cholesterol.**

Regulation of "off-site" testing...

5.5.17 At this point there does not appear to be widespread "off-site" serum cholesterol measurement. In some provinces (Alberta, Ontario and New Brunswick) there are no regulations that would restrict "off-site" testing. In British Columbia, "off-site" testing is prohibited by non-physicians according to the

guidelines of the province's College of Physicians and Surgeons. In Saskatchewan and in Manitoba, anyone may measure blood cholesterol, but only physicians or pathologists may charge the provincial medical insurance schemes. There is or has been "off-site" screening in Manitoba, Ontario and in Quebec under organized programs of research (Ontario, General Motors employees) or of promotion of healthy dietary habits (Provigo in Quebec (Gagnon and Pineau, 1989) (Leroux, 1990)). The Working Group recommends:

> ***Recommendation #15:*** **That provincial and territorial departments of health collaborate with research funding bodies to facilitate studies designed to evaluate the performance of desk-top analyzers and other out of laboratory testing methods under field conditions such as may be found in doctors offices and community testing sites.**

5.5.18 The Working Group has been apprised of the importance that "off-site" testing with desk-top analyzers meet appropriate precision and accuracy standards as are expected from clinical laboratories.

> ***Recommendation #16:*** **That provincial and territorial departments of health, in consultation with medical and professional associations issue quality control guidelines to enable the appropriate utilization of desk-top analyzers if they are to be used in sites other than laboratories.**

5.6 Cost-effectiveness considerations

Population strategy...

5.6.1 In the long term, a population strategy is the most effective way to deal with the cholesterol issue. In practical terms this means that the blood cholesterol level of most Canadians must come down. The population approach is also the most inexpensive strategy in terms of direct costs to the health care system. This is not to say that the population strategy would not generate costs for the food industry or for government. The cost of bringing to market new healthy foods,

changing marketing patterns, and the government support for programs to enable and promote dietary change will be considerable. The Working Group has been made aware of the concerns of the food industry that recommendations for dietary change should not be made frivolously in order to avoid unjustified economic loss to food producers.

Population goal: 4.9 mmol/L...

5.6.2 The Canadian Consensus Conference on Cholesterol (1988) recommended that the average blood cholesterol of Canadians should be reduced from its current level (5.3 mmol/L) to 4.9 mmol/L. This could, in part, be accomplished through the implementation of an effective strategy to bring about dietary change. Simple calculations relating current levels of fat intake to dietary goals and to mean caloric consumption show that the average Canadian needs to cut down about one ounce of dietary fat intake per day. Of this amount, one-third should come from saturated fat sources. Hygienic measures such as increased physical activity and weight control starting early in life play an important part in moving towards the proposed reduction of the average blood cholesterol.

Population impact of dietary change...

5.6.3 A review of estimates of the potential of diet to lower blood cholesterol in free living populations leads the Working Group to the conclusion that effective implementation of the Nutrition Recommendations could realistically, over a five to ten year period, yield an average blood cholesterol reduction in Canadian adults of at least 5%. This represents 0.3 mmol/l or about half the amount required to reach the target goal proposed by the Canadian Consensus Conference on Cholesterol.

Control of other risk factors such as high blood pressure and smoking would add further to the reduction in ischemic heart disease (Little, Horlick, 1989). This would form the basis for a multifactorial population strategy that would address comprehensively the major risk factors for ischemic heart disease.

Population impact of a multifactorial approach...

5.6.4 A simulation study carried out for the Working Group shows that implementation of a comprehensive multifactorial population strategy in Nova Scotia would be expected to yield a reduction of 10% in the number of first ischemic heart disease events experienced by adult men and women, ages 35 to 64, over a period of eight years (Table 4) (MacLean et al.,1990). The population strategy assumes an across-the-board reduction, on every individual, of 5% in the level of blood cholesterol, 3% in

the level of diastolic blood pressure and a 5% smoking cessation rate. The study employs a Montecarlo simulation methodology (MacLean, Petrasovits, 1990), the Nova Scotia Heart Health Data Base (MacLean, Petrasovits, 1988) and predictive equations to calculate the risk of developing ischemic heart disease derived from The Framingham Study (Abbott, McGee, 1987). These projections are consistent with others reported in the literature and show that an overall reduction of 10% in blood cholesterol and a reduction of 5% in diastolic blood pressure, would result in a 33% decrease in cardiovascular disease death rates (Kottke et al., 1985). These estimates of the potential of a population strategy to reduce ischemic heart disease are also consistent with other work which shows that the majority of deaths in a population attributable to elevated blood cholesterol stem from the middle part of the distribution curve of the risk factor; i.e., from the 5.2 to 6.7 mmol/L (Rose, 1981).

Diet before drugs...

5.6.5 The fact that about one in five adults, ages 35-74, has an LDL-cholesterol level over 4.1 mmol/L (a level for which some guidelines recommend drug treatment) suggests a potential for medicalization of large numbers of Canadians (Table 2) (National Cholesterol Education Program, 1988; Canadian Consensus Conference on Cholesterol, 1988). This is due to the difficulty of bringing about significant dietary change in individuals and to the emergence of drug therapies which now make it possible to lower elevated LDL-cholesterol levels in most individuals at risk (Witzum, 1989). It has been shown that significantly lowering blood cholesterol leads to substantial inhibition of the progression of ischemic artery disease (Blackenhorn, 1987). However, advances in the pharmacologic management of hyperlipidemia may lead to aggressive use of drugs in the treatment of individuals with hypercholesterolemia and the early abandonment of dietary approaches. Like all other drugs, hypolipidemic drugs are not without risk as only a limited number of drugs (e.g., cholestyramine) have been in use long enough to evaluate their long-term safety. While the current cost of medication and medical monitoring is substantial (it ranges from $450 to $1,550 per year; Little, 1989) it is comparable to the cost of other treatment programs for other chronic conditions. All this argues for the need to pursue an aggressive dietary approach to lowering blood cholesterol before resorting to the use of drugs.

Studies of cost-effectiveness...

5.6.6 Against this backdrop of potential cost and incomplete knowledge on the value of intervention, it is pertinent to

consider how health care resources may best be used. There are a number of studies on the cost-effectiveness of treating elevated blood cholesterol which have attempted to quantify the value of therapy in terms of cost in dollars per life saved. These studies tend to conclude that: management of hypercholesterolemia among young and middle-aged men is more cost-effective than management of elderly individuals; management of men is more cost-effective than management of women; management of individuals who have more than one risk factor (e.g., also smoke) is more cost-effective than management of individuals with elevated blood cholesterol alone; and that management of individuals with very high levels of blood cholesterol is more cost-effective than management of individuals with moderate to high levels (Weistein, 1985; Kinosian et al., 1988; Oster, 1986, 1987; Office of Management and Budget, 1989).

Assumptions...

5.6.7 Estimates of the cost per life saved vary considerably, e.g., from about $18,000 to $117,000 depending on the therapy used (Kinosian, 1988) and from $36,000 to $1 million depending on the age and sex group considered (Oster, Epstein, 1987). The estimated range of direct and indirect costs and benefits of hypocholesterolemic therapy also vary widely depending on assumptions used. These include: the discount rate; the method of comparison when costs are incurred today but the benefits accrue in future; and the economic value placed on human life (higher for males than for females, higher for the young than for the old) (Dolan et al., 1980). The results from cost-effectiveness studies that place a value on human life should be viewed with caution.

Costs of intervention...

5.6.8 Estimates of the direct costs to the public health and health care systems of the population and the high-risk approaches are given in Table 4. The estimated cost for a population approach is assumed to be less than $1 per capita per year. This is the estimate of the cost of implementing an effective heart health promotion program at national, provincial and community levels. For the high-risk approaches, the costs in Table 4 represent cost per year to the health care system of undertaking to identify for elevated blood cholesterol an adult individual, aged 35 to 74. Note that these are not the costs of treating an individual, but rather the average expected costs associated with the identification of any one individual, including the follow-up that might be required, e.g., referral, retesting, periodic monitoring, nutritional counselling and drug treatment if needed. The expected yearly cost of under-

taking the identification ranges between $110 and $225 per individual initially tested, depending on whether a unifactorial or a multifactorial approach is used. Results from community and individual intervention studies suggest that, for benefits to materialize, interventions and programs need to be sustained, and hence costs are incurred, for a period of 5 to 10 years. More detailed data not presented here show that drugs account for about 80% to 90% of the costs. The estimates in Table 4 have been calculated by averaging out the costs of different paths of management that may be indicated depending on the initial value of blood cholesterol (and the LDL-cholesterol if total cholesterol is elevated), the presence of other risk factors and the probabilities of encountering such patterns of risk in the population. The costs include drugs, physician and specialist visits, laboratory tests, nutrition counselling and smoking cessation estimated for Nova Scotia (MacLean, Petrasovits, 1990).

Assumptions...

5.6.9 The estimates of potential impact and costs of alternative strategies presented in Table 4 depend on the assumptions made to characterize the expected impact of a population and a high-risk intervention on a given individual. The assumptions used to calculate the above estimates are consistent with the experience of reported evaluations of community and individual intervention studies (Puska et al, 1983; Anderson et al., 1973; Langille, Lavigne, 1988; Mann, Marr, 1981; May, 1982; Moser, 1986; Tyroler, 1985, 1987) and also with assumptions made by other studies of the impact of population and high-risk approaches that use similar methodology (Kottke, et al., 1985; National Cholesterol Education Panel, 1990). The estimates in Table 4 depend also on the background population used for the simulation, which in this case is Nova Scotia. However, data from the other Provincial Heart Health Surveys suggest that the rates and the risk factors patterns observed in Nova Scotia are also prevalent in other Canadian provinces (Provincial Heart Health Surveys, 1987-91). In addition, the estimates of impact depend on the equations used to predict risk (Framingham study, Abbott, McGee, 1987), but only minimally on any other mathematical assumptions.

Routine testing now being done...

5.6.10 The policy options available to deal with the cholesterol issue need to recognize that identification of individuals with elevated blood cholesterol is already taking place, primarily through doctors' offices. Data from Provincial Heart Health Surveys (1987-91) show that about 40% of adults report having had their cholesterol level checked. Over 50% of doctors report

routinely measuring blood cholesterol in individuals with one or more risk factors for ischemic heart disease (Battista et al., 1989). The number of blood lipid analyses being done in Canadian laboratories is mounting (Patten, Forest, 1990). Decisions pertaining to the setting of priorities for identification and management of high-risk individuals and groups need to take into account the momentum which already exists.

Need for a comprehensive policy...

5.6.11 The Working Group considers that it is important for provincial jurisdictions to rationalize the utilization of diagnostic and health care resources. Priorities need to be set in the context of a policy that addresses all the different aspects of the cholesterol issue. Identification, evaluation and treatment guidelines are only a part, albeit important part, of a policy. Other necessary components are: an intersectoral approach to bring together the numerous stakeholders involved in the cholesterol issue; promotion and support of enhanced reliability of laboratory analysis of blood lipids which would make identification and evaluation more efficient; professional education and provision of necessary human resources to optimize the effectiveness of the management of hypercholesterolemia and avoid unnecessary medicalization; public education and promotion of dietary change to support and bring about dietary practices in consumers that will reduce the average blood cholesterol level of Canadian adults; and the setting in place of programs for identification and appropriate management of hard-to-reach groups and individuals at high risk.

... to manage the cholesterol issue...

5.6.12 The implementation of a comprehensive public health approach to address the cholesterol issue in Canada requires a proper time horizon. Development of the different components that are needed must go hand in hand with the available resources. The Working Group concludes that to ensure cost-effectiveness it is necessary for Canadian jurisdictions to manage the cholesterol issue. Not to do so will contribute further to the current confusion and will not stop the current escalation of costs. On the other hand, a rational and comprehensive policy would afford a major opportunity to make significant gains in the health of Canadians by the year 2000.

6. SUMMARY OF GOALS AND RECOMMENDATIONS

The Working Group proposes the following goals for the year 2000:

Goal #1: **To reduce substantially the number of Canadians at risk due to elevated blood cholesterol and other risk factors for ischemic heart disease.**

Goal #2: **To reduce the population average blood cholesterol for adult Canadians from the current 5.3 mmol/L to 4.9 mmol/L.**

Goal #3: **To reduce average daily intake of total fat and saturated fat to 30% and 10% respectively of total calories.**

Goal #4: **To have Canadian children adopt healthy eating and physical activity habits, maintain a healthy body weight and avoid smoking.**

The Working Group recommends:

Recommendation #1: **That provincial departments of health assume leadership in developing coalitions and coordinating policy and program development on the different aspects of the cholesterol issue in the context of heart health programs.**

Recommendation #2: **That the federal, provincial and territorial departments of health, relevant voluntary agencies and professional associations develop consistent approaches that make Canadians aware of the meaning of elevated blood cholesterol as a risk factor for ischemic heart disease and advise them of actions they may take to control it.**

Recommendation #3: **That the federal, provincial and territorial departments of health, voluntary health organizations and professional associations: (a) develop partnerships to deliver consistent public education messages on cholesterol; (b) integrate cholesterol messages for delivery in public information programs that address cardiovascular disease risk reduction in a multifactorial manner.**

Recommendation #4: **That the federal, provincial and territorial departments of health, voluntary health agencies and**

professional organizations promote Canada's *Guidelines for Healthy Eating*, and in addition, provide the public with specific, clear and practical information to reduce the consumption of total fat and saturated fat.

Recommendation #5: That the Department of National Health and Welfare monitor nutrition labelling by the food industry; that it implement a program to educate consumers in the use of nutrition labelling and that it evaluate nutrition labelling within five years.

Recommendation #6: That provincial and territorial departments of health develop nutrition policies for their own jurisdictions, which are sensitive to the needs of different cultural and socio-economic groups and which suit their local economies.

Recommendation #7: That provincial and territorial departments of health, in collaboration with the Department of National Health and Welfare, conduct standardized nutrition surveys in their jurisdictions.

Recommendation #8: That the Department of National Health and Welfare support the Canadian Atherosclerosis Society and other relevant professional organizations in the development of guidelines for the evaluation and treatment of hypercholesterolemia in adults.

Recommendation #9: That the professional associations of physicians, nurses and dietitians, the provincial and territorial departments of health and educational institutions develop curricula and continuing education programs to enhance knowledge and skills for identification, evaluation and management of hypercholesterolemia and other ischemic heart disease risk factors.

Recommendation #10: That provincial and territorial departments of health, in consultation with professional associations and educational institutions ensure sufficient community and clinical dietitian internships are available to support nutrition education programs and the demand for dietary counselling.

Recommendation #11: That educational institutions, professional associations and voluntary health agencies support

continuing education activities that reinforce multidisciplinary approaches to cardiovascular disease prevention.

Recommendation #12: **That the Department of National Health and Welfare and the provincial and the territorial departments of health examine the feasibility of establishing and supporting one or more reference laboratories which would standardize clinical laboratories and would produce the reference materials required both for Proficiency Testing programs and the quality control of laboratory analysis of blood lipids.**

Recommendation #13: **That provincial and territorial departments of health encourage the reliability of analysis of blood lipids by requiring laboratories to participate in internal and external quality control programs.**

Recommendation #14: **That provincial and territorial departments of health and professional associations ensure that clinical laboratories, when reporting the results of blood lipid tests to physicians, classify individuals according to the established cut-off points recommended by the Canadian Consensus Conference on Cholesterol.**

Recommendation #15: **That provincial and territorial departments of health collaborate with research funding bodies to facilitate studies designed to evaluate the performance of desk-top analyzers and other out of laboratory testing methods under field conditions such as may be found in doctors offices and community testing sites.**

Recommendation #16: **That provincial and territorial departments of health, in consultation with medical and professional associations issue quality control guidelines to enable the appropriate utilization of desk-top analyzers if they are to be used in sites other than laboratories.**

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LIST OF TABLES

Table 1 **Prevalence of elevated blood cholesterol for two levels by age and sex. (a) (b)**

Sex/Age		5.2-6.2 (mmol/L)	over 6.2 (mmol/L)
		%	%
Male	18-34	21	6
	35-64	35	26
	65-74	40	24
Female	18-34	17	5
	35-64	35	19
	65-74	36	44

(a) Average of prevalence rates from the Provincial Health Surveys (1987-91).

(b) Plasma cholesterol samples measured in fasting samples (8 hours or more).

Table 2 **Prevalence of elevated LDL-cholesterol for two levels by age and sex. (a) (b)**

Sex/Age		3.4 - 4.1 (mmol/L)	over 4.1 (mmol/L)
		%	%
Male	18-34	17	7
	35-64	30	22
	65-74	30	25
Female	18-34	11	4
	35-64	27	17
	65-74	28	39

(a) Average of prevalence rates otained in the Provincial Heart Health Surveys (1987-91).

(b) Measured in fasting samples (8 hours or more).

Table 3 Distribution of individuals with elevated blood cholesterol levels, over age and sex groups. Canada (a) (b)

Sex/Age		5.2-6.2 (mmol/L)	over 6.2 (mmol/L)
		%	%
Male	18-34	13	8
	35-64	31	38
	65-74	6	6
Female	18-34	12	6
	35-64	31	28
	65-74	7	14
		100	100
Total number		5,232,000	3,078,000

(a) Calculated by extrapolating the prevalence rates from Provincial Heart Health Surveys (1987-91) to ten Canadian provinces.

(b) Plasma cholesterol measured in fasting samples (8 hours or more).

Table 4: Impact of population and high risk (unifactorial and multifactorial) approaches on (1) the probability of a first ischemic heart disease event over 8 years (per 1000), (2) average blood cholesterol level, and expected costs per 1000 individuals, for the population approach and the high risk approach (per 1000 individuals identified and followed up on as required). (a) (b)

	Prob/ 1000 pop.	Percent reduction (h) (%)	Average blood cholesterol (mmol/L)	Percent reduction(h) (%)	yearly costs/ 1000 indiv. ($ 000's)
No Intervention	63	-	5.5	-	-
Population alone (c)	57	10	5.2	5	1
High Risk alone:					
- Unifactorial (d)	59	6	5.1	7	113
- Multifactorial (e)	55	13	5.1	7	214
High Risk and Population Combined:					
- Unifactorial (f)	53	16	4.9	11	114
- Multifactorial (g)	50	21	4.9	11	215

(a) Based on data from The Nova Scotia Heart Health Survey for adults ages 35-74; sample sizes are as follows:
n = 345, 112, 377, 110 for males 35-64, 65-74, and females 35-64, 65-74, respectively.

(b) Costs include; drugs, physician/specialist visits, labratory tests, nutrition counselling and smoking cessation/or programs.

(c) Assumes, for each individual in the data base: reduction of blood cholesterol by 5%, blood pressure by 3%, and a 5% rate of smoking cessation.

(d) Assumes reduction of serum bloood cholesterol as follows:

(1) If blood cholesterol is above 5.2 mmol/L: 20% reduction in 50% of individuals, 10% in 30% of individuals and 0% reduction in 20% of individuals.

(2) If blood cholesterol is between 5.2 and 6.2 mmol/L the reduction is: 10% in 50% of individuals, 5% in 30% of individuals, and 0% in 20% of individuals.

(3) For individuals who have blood cholesterol under 5.2 mmol/L, or diastolic blood pressure under 90 mm Hg, or are non-smokers, there is no change in their corresponding risk factors.

(e) Assumes in addition to the unifactorial high risk approach the following: for diastolic blood pressure over 90 mm Hg the reduction is 10% in 50% of individuals, 5% in 30% of individuals, and 0% in 20% of individuals: 50% smoking cessation is also assumed.

(f) Assumes application of the unifactorial approach (as in (d) above) followed by the population approach (as in (c) above).

(g) Assumes application of the multifactorial approach (as in (e) above) followed by the population approach (as in (e) above)

(h) Percent reduction calculated relative to no intervention.

(Adapted from Maclean, Petrasovits, et al., 1990)

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